UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,396	12/18/2001	Kenneth W. Dobie	RTS-0339	5833

7590 11/19/2002

Jane Massey Licata
Licata & Tyrrell, P.C.
66 East Main Street
Marlton, NJ 08053

EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	7

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/024,396	Applicant(s) DOBIE, KENNETH W.	
	Examiner J. Douglas Schultz	Art Unit 1635	

-- The MAILING DATE of this communication appears on th cov r sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-10 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

Newly submitted claim 1 is directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: Amended claim 1 introduces new subject matter in the form of three sequences that have, to date, not appeared in any claim in the instant application, and were not examined in the Office action of June 5, 2002. These sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct due to each having a unique nucleotide sequence. Furthermore, a search of newly added sequences introduced later during prosecution presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one claimed sequence. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, those elements of claim 1 that are drawn to newly introduced sequences, i.e. SEQ ID NOS 10, 12 and 13, are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant's response filed Sept. 5, 2002 has been considered. Rejections and/or objections not reiterated from the previous office action mailed June 5, 2002 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated

and are the only rejections and/or objections presently applied to the instant application. Furthermore, applicant's arguments with respect to claims 15-20 are noted, but are not considered as a results of applicant's cancellation or amendment of said claims.

Applicant's arguments with respect to claims 1 and 2 under 35 USC 102(b), claims 1, 2, 4-10, and 12 –14 under 35 USC 103(a), and claim 15 under 35 USC 112 1st paragraph have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-6, 8-10, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Gimeno et al. (U.S. Patent Number 6,008,014).

The invention of the above claims is drawn to antisense compounds 8-50 nucleotides long that target and inhibit the expression of CD36L1, wherein said compounds comprise specific internucleoside, sugar or nucleobase modifications and chimeras of said antisense compounds.

Gimeno et al. teach antisense compounds that target and inhibit the expression of CD36L1 (SEQ ID NO: 5, and cols. 15 -17), wherein said compounds comprise internucleoside (phosphorothioate, col. 15, lines 25-27), sugar (col. 16, last para.) and nucleobase (5-methylcytosine, col. 16, line 53) modifications.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gimeno et al. (U.S. Patent Number 6,008,014), in view Calvo et al. and Baracchini et al. (U.S. Patent Number 5,801,154).

The claims are drawn to antisense compounds 8-50 nucleobases in length that target and inhibit the expression of CD36L1, and to internucleoside, sugar, or nucleobase modifications and chimeras of said antisense compounds, and compositions providing for their *in vivo* use.

Gimeno et al. teach isolated nucleic acids that target CD36L1 (SR-B1 of Gimeno et al.) and modify its expression. Gimeno et al. does not teach compositions comprising internucleoside, sugar, nucleobase, and 2' modifications, chimeras, and compositions comprising said compounds in pharmaceutical preparations.

Calvo et al. teach the cDNA sequence encoding CD36L1.

Baracchini et al. teaches modifications of antisense compounds comprising sugar, nucleobase, 2' modifications, and chimeras.

It would have been obvious to one of ordinary skill in the art to make antisense oligos to inhibit CD36L1, because antisense inhibition of said transcript had been previously taught by Gimeno et al., and since the cDNA sequence had been previously taught by Calvo et al., allowing one of ordinary skill to further design sequences that target any portion of CD36L1. It

also would have been obvious to one of ordinary skill in the art to formulate internucleoside, sugar, nucleobase, 2', and chimeric modifications and compositions comprising said compounds in pharmaceutical preparations as taught by Baracchini et al. into either the antisense compounds of Gimeno et al., or into those designed from the complementary sequence of CD36L1 as taught by Calvo et al., because Baracchini et al. teach that such modifications increase an antisense compound's cellular uptake, target affinity and resistance to degradation. One would have been motivated to create such compounds because Gimeno et al. teach that inhibiting CD36L1 may counteract cardiovascular disease, aberrent lipid metabolism, metabolic disorders, or atherosclerosis, and since Baracchini et al. teach that introducing modifications to said compounds would prolong the activity of such antisense compounds. Finally, one would have a reasonable expectation of success given that antisense-mediated inhibition of CD36L1 was previously described by Gimeno et al., and since modifications to enhance the activity of antisense compounds as taught by Baracchini et al. are routinely performed by one of ordinary skill in the art.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD
November 15, 2002

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600